

- Group I. Claims 1-5, 7, 9, 11-23, 25-32 and 34-40, drawn to an immunogenic composition comprising a first polypeptide coupled to a second polypeptide wherein the second polypeptide is heterologous to a subject, the composition being capable of eliciting an immune response against an autologous antigen in the subject wherein the autologous antigen is a cell-associated or soluble antigen, classified in Class 424, subclass 192.1.
- Group II. Claims 1-4,6,9,11-20,23,25-31, and 34-40, drawn to an immunogenic composition comprising a first polypeptide coupled to a second polypeptide wherein the second polypeptide is heterologous to a subject, the composition being capable of eliciting an immune response against an autologous antigen in the subject wherein the autologous antigen is a cell surface receptor, classified in Class 424, subclass 192.1
- Group III. Claims 1-4, 8-9, 11-20, 23, 25-31, and 34-40, drawn to an immunogenic composition comprising a first polypeptide coupled to a second polypeptide wherein the second polypeptide is heterologous to a subject, the composition being capable of eliciting an immune response against an autologous antigen in the subject wherein the autologous antigen is a cytokine, classified in Class 424, subclass 192.1.
- Group IV. Claims 1-4, 8-9, 11-20,23, 25-31, and 34-40, drawn to an immunogenic composition comprising a first polypeptide coupled to a second polypeptide wherein the second polypeptide is heterologous to a subject, the composition being capable of eliciting an immune response against an autologous antigen in the subject wherein the autologous antigen is a hormone, classified in Class 424, subclass 192.1.
- Group V. Claims 1-4, 10-20, 24-31, and 33-40, drawn to an immunogenic composition comprising a first polypeptide coupled to a second polypeptide wherein the second polypeptide is heterologous to a subject, the composition being capable of eliciting an immune response against an autologous antigen in the subject wherein the autologous antigen is a tumor antigen, classified in Class 424, subclass 192.1.
- Group VI. Claims 41-43, drawn to a nucleic acid molecule encoding a recombinant construct comprising a human polypeptide coupled to a non-human polypeptide, the construct being capable of eliciting an immune response against said human polypeptide, a vector and a host comprising said recombinant construct, classified in Class 424, subclass 185.1.
- Group VII. Claims 44-50 and 52-54, drawn to a method of inducing an immune response against an autologous antigen associated with a disorder in a

subject comprising administering to said subject an immunogenic composition comprising a first autologous polypeptide coupled to a second heterologous polypeptide wherein the disorder is cancer, classified in Class 424, subclass 185.1.

Group VIII. Claims 44-52 and 54-59, drawn to a method of inducing an immune response against an autologous antigen associated with a disorder in a subject comprising administering to said subject an immunogenic composition comprising a first autologous polypeptide coupled to a second heterologous polypeptide wherein the disorder is allergy, classified in Class 424, subclass 185.1.

Group IX. Claims 44-52 and 54-59, drawn to a method of inducing an immune response against an autologous antigen associated with a disorder in a subject comprising administering to said subject an immunogenic composition comprising a first autologous polypeptide coupled to a second heterologous polypeptide wherein the disorder is arthritis, classified in Class 424, subclass 185.1.

Group X. Claims 44-52 and 54-59, drawn to a method of inducing an immune response against an autologous antigen associated with a disorder in a subject comprising administering to said subject an immunogenic composition comprising a first autologous polypeptide coupled to a second heterologous polypeptide wherein the disorder is atherosclerosis, classified in Class 424, subclass 185.1.

Group XI. Claims 44-52 and 54-59, drawn to a method of inducing an immune response against an autologous antigen associated with a disorder in a subject comprising administering to said subject an immunogenic composition comprising a first autologous polypeptide coupled to a second heterologous polypeptide wherein the disorder is graft rejection, classified in Class 424, subclass 185.1.

Group XII. Claims 44-52 and 54-59, drawn to a method of inducing an immune response against an autologous antigen associated with a disorder in a subject comprising administering to said subject an immunogenic composition comprising a first autologous polypeptide coupled to a second heterologous polypeptide wherein the disorder is inflammatory disease, classified in Class 424, subclass 185.1.

It is the Examiner's position that the inventions of Groups I-V are distinct because "the products as claimed such as fusion or conjugate polypeptide (antigen, receptor, cytokine, tumor

antigen versus hormone) and nucleic acid differ with respect to structure and physiochemical properties." The Examiner is further of the opinion that the inventions of Groups VII-XII are distinct because "the methods of inducing an immune response or reducing antibody using a distinct product for treating a specific disease that differ with respect to their etiology differ with respect [to] process steps and therapeutic endpoints." The Examiner concludes that since "these inventions are distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper."

Applicants hereby elect *with traverse* Group I (Claims 1-5, 7, 9, 11-23, 25-32 and 34-40) for prosecution on the merits. Applicants traverse the restriction requirement to the extent that Groups I, II, III, IV and V should be reformed as a single group containing claims 1-40 (referred to hereinafter as "newly formed Group I"). Applicants' grounds for traversal are set forth in detail below.

Applicants have presented an allowable generic linking claim, *i.e.*, claim 1, which is generic to the claims set forth in Groups I-V proposed by the Examiner. Claim 1 is drawn to an immunogenic composition, comprising a first polypeptide coupled to a second polypeptide, wherein the second polypeptide is heterologous to a subject, the composition being capable of eliciting an immune response against an autologous antigen in the subject. Accordingly, it is Applicants' position that given the presence of claim 1, which is generic to Groups I-V proposed by the Examiner, a restriction under 35 U.S.C. §121 is improper. Claim 1 embraces the species of: a cell-associated or soluble antigen, a cell surface receptor, a cytokine, a hormone and a tumor cell antigen. In view of the above traversal, Applicants hereby elect *newly formed Group I*, *i.e.*, claims 1-40 for prosecution on the merits.

Moreover, Applicants respectfully submit that a sufficient search and examination with respect to the inventions of Groups I-V can be made without serious burden on the Examiner. M.P.E.P. § 803 states:

[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.  
M.P.E.P. § 803.

A search of the prior art relating to the invention of the Groups proposed by the Examiner would certainly be co-extensive with each other and, thus, would not involve a serious burden on the Examiner. Indeed, Applicants note that the inventions of Groups I -V are classified in the same search, *i.e.*, class 424, subclass 192.1. Applicants therefore request that the Examiner examine Groups I-V together as a single invention.

With respect to the non-elected Groups, Applicants respectfully submit that Groups VII, VIII, XI, X, XI and XII should be reformed as a single group containing claims 44-59.

#### Species Election

The Examiner has further required that Applicants elect, under 35 U.S.C. § 121, a single disclosed species for prosecution on the merits. The Examiner indicates that if "Group I, II, III, IV or V is elected, the Applicants are required to elect a specific immunogenic composition comprising (1) a specific first autologous polypeptide, or a specific autologous antigen such as the ones recited in claims 9, 17, 23, 24 and 28 (2) a specific second heterologous polypeptide such as the ones recited in claims 18 and 19." The Examiner further asserts that the "specific first polypeptides differ with respect to their binding specificity and immune function while the second polypeptides differ with respect to their structures and immune functions."

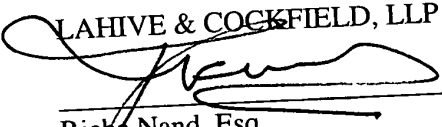
With respect to this species election Applicants further elect the species CD79 $\alpha$  (Ig $\alpha$ ) for the first polypeptide and the species of IgG Fc for the second polypeptide for search purposes only. It is Applicants' understanding that the species election is for searching purposes only, and upon a finding of allowability of the elected species, the remaining species also will be searched.

**CONCLUSION**

Applicants respectfully submit that the application is now in condition for allowance. If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the examiner is urged to call Applicants' Attorney at (617) 227-7400.

Respectfully submitted,

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Date: **December 4, 2002**